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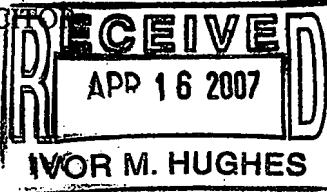
## NOTICE OF ALLOWANCE AND FEE(S) DUE

23607

7590

03/30/2007

IVOR M. HUGHES, BARRISTER & SOLICITOR  
PATENT & TRADEMARK AGENTS  
175 COMMERCE VALLEY DRIVE WEST  
SUITE 200  
THORNHILL, ON L3T 7P6  
CANADA



EXAMINER

POWERS, FIONA

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 03/30/2007

Due: July 2/07

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/501,770	08/10/2006	Eckardt C. G. Wolf	PT-2147001	5872

TITLE OF INVENTION: NOVEL AND SAFE PROCESS FOR THE PREPARATION OF BALSALAZIDE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1400	\$300	\$0	\$1700	07/02/2007

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

## HOW TO REPLY TO THIS NOTICE:

## I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
- B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

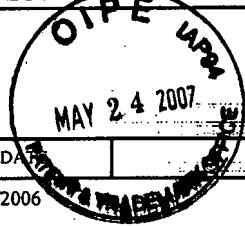
II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



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11/501,770	08/10/2006	Eckardt C. G. Wolf	PT-2147001	5872

23607 7590 03/30/2007

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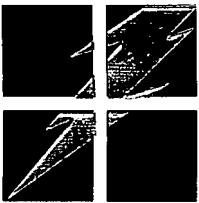
**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**  
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.



# Ivor M. Hughes

Barrister & Solicitor

Patent & Trade Mark Agents  
Canada, United States



Our Ref.: PT-2147001

Via Courier

May 23, 2007

The Commissioner of Patents  
United States Patent Office  
Customer Service Window, Mail Stop ISSUE FEE  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314  
U.S.A.

Dear Sir:

**Re: United States Patent Application Serial No. 11/501,770**  
**Applicant: Apotex Pharmachem Inc.**  
**Title: NOVEL AND SAFE PROCESS FOR THE PREPARATION OF**  
**BALSALAZIDE**  
**CUSTOMER NO. 23607**  
**DUE DATE: July 2, 2007**

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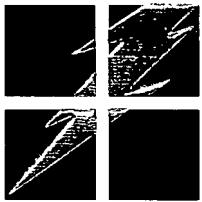
Pursuant to the Notice of Allowance dated March 30, 2007, a copy of which Notice is enclosed herewith for your reference, Applicant encloses a cheque in the amount of **\$1,700.00 USD** made payable to "The Commissioner of Patents" which sum is comprised of the issue fee (\$1,400.00 USD) and publication fee (\$300.00 USD) for a large entity. Should there occur an overpayment or underpayment of fees in respect of this application, the Commissioner is authorized to access Deposit Account Number 08-3255 to make the appropriate adjustments.

Applicant also submits a completed PTOL-85 Issue Fee Transmittal Form.

Also enclosed herewith is a stamped, self-addressed verification card which we request that you date-stamp and return to this office at the earliest opportunity.

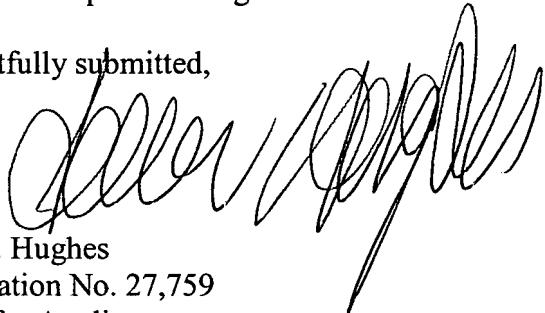
**Barristers & Solicitors**  
Ivor M. Hughes  
Rick Tuzi

**Patent Agents**  
Neil H. Hughes, P.Eng.  
Marcelo K. Sarkis, P.Eng.  
Wm. Kitt Sinden  
Samuel T. Tekie, P.Eng.  
Francis Ng-Cheng-Hin



We thank the Commissioner for his cooperation in this regard and look forward to obtaining an issue fee receipt in this regard.

Respectfully submitted,



Ivor M. Hughes  
Registration No. 27,759  
Agent for Applicant

IMH/mr

Enclosures

- 1) Cheque \$1,700.00 USD
- 2) Verification Card
- 3) Form PTOL-85
- 4) Copy of Notice of Allowance



## Notice of Allowability

Application No.	Applicant(s)
11/501,770	WOLF ET AL.
Examiner	Art Unit
Fiona T. Powers	1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to amendment and drawings filed March 6, 2007.

2.  The allowed claim(s) is/are 1-19.

3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of the:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.

(b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 20070328.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other See Continuation Sheet.

**Continuation of Attachment(s) 9. Other:** the drawings filed 3/6/07 are accepted by the examiner.

Art Unit: 1626



**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andre Lapierre on March 28, 2007.

The application has been amended as follows:

Claim 6, line 1, delete "1, 2, 3, 4 or 5" and insert -1, 2 or 3-.

Claim 7, line 1, delete "1, 2, 3, 4, 5 or 6" and insert -1, 2 or 3-.

Claim 8, line 1, delete "1, 2, 3, 4, 5, 6 or 7" and insert -1, 2 or 3-.

Claim 9, line 1, delete "1, 2, 3, 4, 5, 6, 7 or 8" and insert -1, 2 or 3-.

Claim 15, line 2, delete "any of the previous claims" and insert -claim 10, 11 or 12-.

Claim 16, line 2, delete "any of the previous claims" and insert -claim 10, 11 or 12-.

Claim 17, line 2, delete "any of the previous claims" and insert -claim 10, 11 or 12-.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: the prior art of record does not anticipate or render obvious the claimed process for the preparation of Balsalazide or the methanesulfonate and p-toluenesulfonate salts of N-(4-diazoniumbenzoyl)- $\beta$ -alanine. The closest prior art process is disclosed in Example 4 of U.S. Patent 4,412,992 and Shan et al., Shi et al., Chai et al. and Su et al. The processes disclosed in these references does not comprise the conversion of N-(4-aminobenzoyl)- $\beta$ -alanine to N-(4-ammoniumbenzoyl)- $\beta$ -alanine sulfonate salt. These references disclose the chloride salt of N-(4-diazoniumbenzoyl)- $\beta$ -alanine but do not disclose its methanesulfonate or p-toluenesulfonate salts. The references provide no motivation to modify the process and compounds disclosed therein to arrive at the claimed process and compounds.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T.

Art Unit: 1626

Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Fiona T. Powers*  
Fiona T. Powers  
Primary Examiner  
Art Unit 1626

ftp  
March 28, 2007

<b>Examiner-Initiated Interview Summary</b> 		Application No. 11/501,770	Applicant(s) WOLF ET AL
		Examiner Fiona T. Powers	Art Unit 1626
<b>All Participants:</b> (1) <u>Fiona T. Powers</u> . (2) <u>Andre Lapierre</u> .		<b>Status of Application:</b> _____ (3) _____. (4) _____. <b>Date of Interview:</b> <u>28 March 2007</u>	
<b>Type of Interview:</b> <input checked="" type="checkbox"/> Telephonic <input type="checkbox"/> Video Conference <input type="checkbox"/> Personal (Copy given to: <input type="checkbox"/> Applicant <input type="checkbox"/> Applicant's representative)			
<b>Exhibit Shown or Demonstrated:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes, provide a brief description: _____			
<b>Part I.</b>			
<b>Rejection(s) discussed:</b> NONE.			
<b>Claims discussed:</b> 6-9 and 15-17			
<b>Prior art documents discussed:</b> NONE			
<b>Part II.</b> <b>SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL NATURE OF WHAT WAS DISCUSSED:</b> <i>See Continuation Sheet</i>			
<b>Part III.</b>			
<input checked="" type="checkbox"/> It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Allowability. <input type="checkbox"/> It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview did not result in resolution of all issues. A brief summary by the examiner appears in Part II above.			
<b>(Examiner/SPE Signature)</b>		<b>(Applicant/Applicant's Representative Signature – if appropriate)</b>	

Continuation of Substance of Interview including description of the general nature of what was discussed: The examiner contacted Mr. Lapierre to inform him that the application would be in condition for allowance if the following were done: 1)claims 6 to 9, change the dependency to -claim 1, 2 or 3- and 2)claims 15 to 17, change the dependency to -claim 10, 11 or 12-. It was agreed that claims 6 to 9 and 15 to 17 would be amended as discussed above by examiner's amendment..